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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,374	06/08/2001	Jeffrey C. Rapp	AVI-007N	2448

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EXAMINER	
TON, THAIAN N	
ART UNIT	PAPER NUMBER
1632	

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01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/877,374	RAPP, JEFFREY C.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9-29,62-70,72 and 74-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 9-29, 62-70, 72, 74-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/08 has been entered.

Applicants' Response and Amendment, filed 12/19/08, has been entered. Claims 76 is newly added; claims 1-5, 9-29, 62-70, 72, 74-76 are pending and under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 76 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Applicants have added claim 76 to recite that the heterologous antibody lacks fucose. The Examiner is unable to locate any support for the newly claimed embodiment, and therefore, this limitation introduces new-matter into the as-filed disclosure.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claim 76 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP §2163.06 notes:
If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:
Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:
When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9-17, 19-29, 62, 63, 74 and newly added claim 76 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio et al. when taken with Sanders et al. in further view of Mohammed et al. and in further view of Michael et al. as further evidenced by WO 99/19472 (published April 22, 1999). This rejection is maintained for reasons of record.

Applicants' Arguments. Applicants argue that it has been determined that proteins produced in avian oviduct cells (i.e., tubular gland cells) are not fucosylated. Applicants provide Zhu (2005) and Raju et al (2000) and state that this lack of fucosylation in the oviduct cells of chickens is in contrast to what is seen in other cells of the chicken. Applicants argue that this absence of fucose alters the therapeutic utility of monoclonal antibodies by increasing their potency, and provide Etches (2006) as support.

Response to Arguments. These arguments are not persuasive. Firstly, the Examiner notes that the cited art of record is not commensurate in scope with the claims, and therefore, not commensurate in scope with the unexpected result. In particular, the breadth of the claims is directed to producing a heterologous antibody by any species of avian oviduct cell. However, the art of Zhu, Raju and Etches are only directed to chicken oviduct cells. Additionally, it appears that the claims are not commensurate in scope because the art of Zhu (cited by Etches) discusses the production of heterologous antibodies by injection of the OVA cell line to produce chimeric chickens, wherein the expression of the antibodies was analyzed in the chimeric chickens (see, p. 1160, for example). That is, Zhu is discussing producing heterologous antibodies in a chicken bioreactor, which is not analogous to producing heterologous antibodies in culture, which is the instantly claimed invention. Therefore, the art of Zhu does not overcome the instant rejection because it is not commensurate in scope to that which Applicants claim is unexpected. Additionally, Raju is not commensurate in scope because they discuss

cells other than avian oviduct cells, and the fucosylation that occurs in the proteins produced by other cell types. Although Raju teaches that serum of chickens were known at the time of the invention to contain fucose, this does not provide a nexus with regard to Applicants' invention, because Raju provide no guidance to show that there would be any unpredictability in producing monoclonal antibodies in avian oviduct cells. Additionally, Raju are not looking at the ability for avian oviduct cells to product monoclonal antibodies. Finally, it is noted that because Applicants' methods are not distinguished from that of the prior art, the combination of art is sufficient to render the claimed invention obvious. That is, there is no unexpected result in the production of a heterologous antibody utilizing an avian oviduct cell. Although the post filing art of Zhu may teach an increased potency in the resultant antibody, there is nothing in the claims that requires this increased potency, the claims merely require production of a heterologous antibody; therefore, the combined art of record would reasonably arrive at the claimed invention. Accordingly, the cited art fails to overcome the prior rejection of record.

Applicants' Arguments. Applicants argue that the claims are not required to recite an increase in potency and that the advantage of the method (production of afucosylated antibodies) is inherent, and that it is known that afucosylated antibodies can have an increased activity. Applicants argue that evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded.

Response to Arguments. These arguments are not persuasive. The cited art of record provides sufficient guidance and motivation to show that one of skill in the art could reasonably arrive at the claimed invention, *i.e.*, producing a heterologous antibody by an avian oviduct cell, with a reasonable expectation of success. If the property of lack of fucosylation and increased potency of the antibody is considered an inherent property, as argued by Applicants, then the combination of art would similarly, and inherently, arrive at this conclusion. The method, as claimed, does

not distinguish from the cited art of record, and therefore, would necessarily result in the production of antibodies that lack fucosylation and have increased potency, because the art teaches utilizing the same cells as Applicants' invention. If a property of the avian oviduct cell is such that it does not fucosylate antibodies, then this property would be present in any heterologous antibody produced by an avian oviduct cell.

It is reiterated that the claimed invention is not commensurate in scope with the unexpected result; Applicants have failed to distinguish their methods from those of the combined art, therefore, because the combined art provides the requisite teachings and motivation, it is maintained that this rejection is proper. Although Applicants do not need to recite the advantageous feature of the product that is produced by a method in a particular method claim, because Applicants' method steps result in a heterologous antibody, which is no more than what is taught in the art, the rejection is maintained.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over over Ditullio et al. when taken with Sanders et al. in further view of Mohammed et al. and in further view of Michael et al. as further evidenced by WO 99/19472 (published April 22, 1999), as applied to claims 1-5, 9-17, 19-29, 62, 63 and newly added above, and further in view of Larocca *et al.*.

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Claims 64-70, 72 and newly added claim 75 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio *et al.* when taken Sanders, in further view of Mohammed, and in further view of Michael *et al.* as further evidenced by WO 99/19472 (published April 22, 1999), as applied to claims 1-5, 9-

17, 19-29, 62, 63 and newly added claim 74 above, and further in view of Ling *et al.* and Najarfian *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632